UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 25, 2021

ADMA BIOLOGICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-36728	56-2590442
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

465 State Route 17, Ramsey, New Jersey	07446
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (201) 478-5552

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ADMA	Nasdaq Global Market
Preferred Share Purchase Rights	—	Nasdaq Global Market

Item 2.02 Results of Operations and Financial Condition

On March 25, 2021, ADMA Biologics, Inc. issued a press release announcing its financial results for the three months and year ended December 31, 2020 and providing an overview of recent progress and accomplishments. A copy of the press release is furnished herewith as Exhibit 99.1.*

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	ADMA Biologics, Inc. Press Release, dated March 25, 2021
104	Cover Page Interactive Data File (embedded with the Inline XBRL Document)

* The information in Item 2.02 of this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

March 25, 2021

ADMA Biologics, Inc.

By: /s/ Brian Lenz

Name: Brian Lenz

Title: Executive Vice President and Chief Financial Officer

ADMA Biologics Reports Fourth Quarter and Full Year 2020 Financial Results

Achieved Full Year 2020 Total Revenues of $42.2 Million, a 44% Increase Over Full Year 2019

Accelerated ADMA BioCenters Plasma Collection Network Expansion Guidance; Anticipates Having 10 or More Plasma Collection Centers in Operation by 2024

Management to Host Conference Call and Webcast Today at 4:30 p.m. ET

RAMSEY, NJ and BOCA RATON, FL – March 25, 2021 – ADMA Biologics, Inc. (Nasdaq: ADMA) ("ADMA" or the "Company"), an end-to-end commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics, today reported financial results for its fiscal fourth quarter and year ended December 31, 2020 and provided an overview of recent progress and accomplishments.

"In a year full of unprecedented health and economic challenges due to the pandemic, the ADMA team's unwavering commitment produced remarkable achievements across all our business segments," said Adam Grossman, President and Chief Executive Officer of ADMA Biologics. "Operationally, while enacting all the medically recommended COVID-19 safeguards to protect our patients, employees and customers, we successfully expanded our plasma collection center network ahead of schedule and delivered on all of our manufacturing and regulatory objectives as a part of our supply chain enhancement initiatives. We generated record revenues of $42.2 million despite COVID-19 headwinds, and because of our strong commercial execution, we confidently provided first-time peak annual revenue guidance of $250 million or greater expected to be achieved in 2024 and additionally committed to reaching profitability no later than the first quarter of 2024."

"On the financial front, we substantially strengthened our balance sheet with year-end 2020 assets totaling $207.7 million, significantly growing inventories to a year-end balance of $81.5 million as well as increasing accounts receivable and investments in property, plant and equipment. We look forward to continuing to deliver quarter-over-quarter revenue growth and execute on our strategy during 2021, building on the momentum created by 2020's achievements across all of our business segments," concluded Mr. Grossman.

Select 2020 Achievements & Recent Corporate Developments:

- **Executed Commercially with Significant Year-Over-Year Revenue Growth.** Achieved full year 2020 total revenues of $42.2 million, compared to $29.3 million for the full year 2019, reflecting a substantial 44% increase. Achieved fourth quarter 2020 total revenues of $14.0 million, compared to $12.0 million for the fourth quarter of 2019, representing an approximately 16% increase.

- **Substantially Increased Inventory Levels.** Grew inventories to a year-end 2020 balance of $81.5 million compared to $53.1 million at year-end 2019, which we regard as a solid basis to support our anticipated quarter-over-quarter revenue growth in 2021 and beyond. This inventory consists of raw materials, including source plasma, work-in-process and finished goods.

- **Refinanced Senior Secured Term Loan.** Refinanced senior secured term loan with Perceptive Advisors, which among other things, lowered the effective cost of capital, consolidated ADMA's long-term debt and provided for a two-year extension of the interest-only period through March 2024, which we believe will allow ADMA to reach profitability prior to maturity.

- **Expanded Plasma Collection Center Network.** With the approval of another plasma collection facility in early February, ADMA now has seven plasma collection facilities under its corporate umbrella at various stages of development and approval, including one facility pending Biologics License Application ("BLA") approval in the second half of this year, and two additional plasma collection centers which we intend to open and file BLAs during 2021. Accordingly, we have revised our previous guidance from building 5-10 plasma collection facilities by 2024 to our current expectation of having 10 or more plasma collection facilities in operation by 2024.

- **Advanced Supply Chain Enhancement Initiatives.** We remain on track to receive potential United States Food and Drug Administration ("FDA") approval decisions mid-year for our Intravenous Immune Globulin ("IVIG") increased production capacity scale, as well as our in-house Vanrx aseptic fill-finish machine. Upon FDA approval, ADMA expects to realize significant operating efficiencies and improved gross margins beginning potentially as early as mid-2021, which will ultimately support durable profitability and a fully vertically integrated value chain.

- **Strengthened ASCENIV's Coverage and Patient Access.** Secured a permanent J-code, to be effective April 1, 2021, which will provide for a streamlined and permanent reimbursement process in outpatient treatment settings.

- **Continued Medical Community Engagement.** At the recent American Academy of Allergy, Asthma & Immunology Conference ("AAAAI"), ADMA presented a late-breaking abstract detailing data that underscore the exciting prospect of bridging vaccination and protective seroconversion with a targeted, plasma-derived hyperimmune anti S. *pneumonia* globulin to ensure protection against infection for at-risk patients in the hospital and outpatient settings. Our existing intellectual property portfolio includes issued patents on the composition of matter and methods of use for producing a standardized hyperimmune globulin targeted to the most common 23 serotypes of *S. pneumoniae* bacteria. We will continue to evaluate opportunities to expand our pipeline and future product offerings to maximize value for our shareholders.

- **Received Several Industry Awards.** Our organization's 2020 achievements were recognized in the form of several third-party accolades, including receiving the BioNJ Innovator of the Year Award, being included on the Deloitte Fast 500 List as well as in 2021 our CEO being voted a Top 10 Biotech Executive by Healthcare Technology Report.

Fourth Quarter 2020 Financial Results

Total revenues for the quarter ended December 31, 2020 were $14.0 million, compared to $12.0 million for the quarter ended December 31, 2019, representing an increase of approximately $2.0 million, or approximately 16%. The revenue growth for the fourth quarter of 2020, compared to the fourth quarter of 2019, was favorably impacted by the continued commercial ramp up of our IVIG product portfolio.

Consolidated net loss for the quarter ended December 31, 2020 was $19.4 million, or $(0.20) per basic and diluted share, compared to a consolidated net loss of $10.6 million, or $(0.18) per basic and diluted share, for the quarter ended December 31, 2019. The $8.8 million increase in net loss compared to the prior year period was primarily attributable to increased cost of product revenue of $7.4 million; increases in selling, general and administrative expenses of $2.3 million related to employee compensation, new hires along with other costs to support the commercialization efforts for BIVIGAM® and ASCENIV™ and a $0.5 million increase in research and development expenses mainly related to increased costs associated with clinical studies. The increased net loss additionally includes $1.1 million in higher plasma center operating expenses due to the opening of additional plasma centers during 2020. Included in the net loss for the fourth quarter of 2020 were non-cash expenses of approximately $2.4 million for stock-based compensation, depreciation and amortization, and non-cash interest expense.

Full Year 2020 Financial Results

Total revenues for the year ended December 31, 2020 were $42.2 million, compared to $29.3 million for the year ended December 31, 2019, representing an increase of $12.9 million, or 44%. The increase in revenues was primarily attributable to increased sales of our IVIG products portfolio offset by lower plasma collection revenues.

Consolidated net loss for the year ended December 31, 2020 was approximately $75.7 million, or $(0.88) per basic and diluted share, compared to a consolidated net loss of $48.3 million, or $(0.89) per basic and diluted share, for the year ended December 31, 2019. The increase in net loss of approximately $27.4 million was primarily attributable to a $21.8 million increase in cost of product revenue, which reflects the increase in sales volume as well as $7.5 million of non-recurring production charges incurred for the manufacturing of BIVIGAM conformance lots at an increased plasma pool production scale in connection with our planned capacity expansion. The increase in net loss in 2020 was also attributable to increased selling, general administrative expenses of approximately $9.1 million related to the overall growth in the size and scope of the Company's operations, including the commercialization efforts of BIVIGAM® and ASCENIV™; a $3.6 million increase in research and development expenses associated with the validation for a capacity expansion of a new filling line and increases in various clinical research activities, some of which are required by the FDA. Included in the net loss for the year ended 2020 were non-cash expenses of $8.6 million for stock-based compensation, depreciation and amortization and non-cash interest expense.

At December 31, 2020, ADMA had cash and cash equivalents of $55.9 million and accounts receivable of $13.2 million, compared to cash and cash equivalents of $26.8 million and accounts receivable of $3.5 million at December 31, 2019. ADMA's net working capital as of December 31, 2020 was $133.8 million, compared to $71.8 million as of December 31, 2019.

Conference Call Information

ADMA will host a conference call today, March 25, 2021, at 4:30 p.m. Eastern Time, to discuss the fiscal fourth quarter and full year 2020 financial results and recent corporate updates. To access the conference call, please dial (855) 884-8773 or (615) 622-8043 (international) at least 10 minutes prior to the start time and refer to conference ID 5109699. A live audio webcast of the call will be available under "Events & Webcasts" in the Investor section of the Company's website, https://ir.admabiologics.com/events-webcasts. An archived webcast will be available on the Company's website approximately two hours after the event.

About BIVIGAM®

BIVIGAM (immune globulin intravenous, human – 10% liquid) is a plasma-derived, polyclonal, intravenous immune globulin (IVIG). BIVIGAM was approved by the FDA in May 2019 and is indicated for the treatment of primary humoral immunodeficiency (PI), including, but not limited to the following group of genetic disorders: X-linked and congenital agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome and severe combined immunodeficiency. BIVIGAM contains a broad range of antibodies similar to those found in normal human plasma. These antibodies are directed against bacteria and viruses and help to protect PI patients against serious infections. BIVIGAM is a purified, sterile, ready-to-use preparation of concentrated human Immunoglobulin antibodies. Certain data and other information about BIVIGAM® or ADMA Biologics and its products can be found on the Company's website at www.admabiologics.com.

About ASCENIV™

ASCENIV (immune globulin intravenous, human – slra 10% liquid) is a plasma-derived, polyclonal, intravenous immune globulin (IVIG). ASCENIV was approved by the FDA on April 1, 2019 and is indicated for the treatment of primary humoral immunodeficiency (PI), also known as primary immune deficiency disease (PIDD), in adults and adolescents (12 to 17 years of age). ASCENIV is manufactured using ADMA's unique, patented plasma donor screening methodology and tailored plasma pooling design, which blends normal source plasma and respiratory syncytial virus (RSV) plasma obtained from donors tested using the Company's proprietary microneutralization assay. ASCENIV contains naturally occurring polyclonal antibodies, which are proteins that are used by the body's immune system to neutralize microbes, such as bacteria and viruses and prevent against infection and disease. ASCENIV is protected by U.S. Patents: 9,107,906, 9,714,283 and 9,815,886. Certain data and other information about ASCENIV™ or ADMA Biologics and its products can be found on the Company's website at www.admabiologics.com.

About Nabi-HB®

Nabi-HB® is a hyperimmune globulin that is rich in antibodies to the Hepatitis B virus. Nabi-HB® is a purified human polyclonal antibody product collected from plasma donors who have been previously vaccinated with a Hepatitis B vaccine. Nabi-HB® is indicated for the treatment of acute exposure to blood containing Hepatitis B surface antigen (HBsAg), prenatal exposure to infants born to HBsAg-positive mothers, sexual exposure to HBsAg-positive persons and household exposure to persons with acute Hepatitis B virus infection. Hepatitis B is a potentially life-threatening liver infection caused by the Hepatitis B virus. It is a major global health problem and can cause chronic infection and put people at high risk of death from cirrhosis and liver cancer. Nabi-HB® has a well-documented record of long-term safety and effectiveness since its initial market introduction. Certain data and other information about Nabi-HB® or ADMA Biologics and its products can be found on the Company's website at www.admabiologics.com.

About ADMA BioCenters

ADMA BioCenters is an FDA licensed facility specializing in the collection of human plasma used to make special medications for the treatment and prevention of diseases. Managed by a team of experts who have decades of experience in the specialized field of plasma collection, ADMA BioCenters provides a safe, professional and pleasant donation environment. ADMA BioCenters strictly follows FDA regulations and guidance and enforces cGMP (current good manufacturing practices) in all of its facilities. For more information about ADMA BioCenters, please visit www.admabiocenters.com.

About ADMA Biologics, Inc. (ADMA)

ADMA Biologics is an end-to-end American commercial biopharmaceutical company dedicated to manufacturing, marketing and developing specialty plasma-derived biologics for the treatment of immunodeficient patients at risk for infection and others at risk for certain infectious diseases. ADMA currently manufactures and markets three United States Food and Drug Administration (FDA) approved plasma-derived biologics for the treatment of immune deficiencies and the prevention of certain infectious diseases: BIVIGAM® (immune globulin intravenous, human) for the treatment of primary humoral immunodeficiency (PI); ASCENIV™ (immune globulin intravenous, human – slra 10% liquid) for the treatment of PI; and NABI-HB® (hepatitis B immune globulin, human) to provide enhanced immunity against the hepatitis B virus. ADMA manufactures its immune globulin products at its FDA-licensed plasma fractionation and purification facility located in Boca Raton, Florida. Through its ADMA BioCenters subsidiary, ADMA also operates as an FDA-approved source plasma collector in the U.S., which provides a portion of its blood plasma for the manufacture of its products. ADMA's mission is to manufacture, market and develop specialty plasma-derived, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases and management of immune compromised patient populations who suffer from an underlying immune deficiency, or who may be immune compromised for other medical reasons. ADMA has received U.S. Patents: 9,107,906, 9,714,283, 9,815,886, 9,969,793 and 10,259,865 related to certain aspects of its products and product candidates. For more information, please visit www.admabiologics.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements" pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, about ADMA Biologics, Inc. ("we," "our" or the "Company"). Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain such words as "estimate," "project," "intend," "forecast," "target," "anticipate," "plan," "planning," "expect," "believe," "will," "should," "could," "would," "may," or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements also include, but are not limited to, statements about ADMA's future results of operations, including our anticipated timing for reaching profitability; the goal of building and opening new plasma collection centers by 2024; the outcome and timing of our BLA application for our new plasma centers; and our continued evaluation of opportunities to expand our pipeline and future product offerings. Actual events or results may differ materially from those described in this document due to a number of important factors. Current and prospective security holders are cautioned that there also can be no assurance that the forward-looking statements included in this press release will prove to be accurate. Except to the extent required by applicable laws or rules, ADMA does not undertake any obligation to update any forward-looking statements or to announce revisions to any of the forward-looking statements. Forward-looking statements are subject to many risks, uncertainties and other factors that could cause our actual results, and the timing of certain events, to differ materially from any future results expressed or implied by the forward-looking statements, including, but not limited to, the risks and uncertainties described in our filings with the U.S. Securities and Exchange Commission, including our most recent reports on Form 10-K, 10-Q and 8-K, and any amendments thereto.

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ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Year Ended December 31,	
	2020	**2019**	**2020**	**2019**
REVENUES:				
Product revenue	$ 13,920,378	$ 12,001,340	$ 42,076,949	$ 29,206,249
License revenue	35,709	35,709	142,834	142,834
Total Revenues	13,956,087	12,037,049	42,219,783	29,349,083
OPERATING EXPENSES:				
Cost of product revenue	19,111,107	11,691,603	61,291,426	39,504,238
Research and development	1,013,464	464,823	5,907,013	2,343,848
Plasma center operating expenses	1,572,607	464,131	4,170,051	2,169,629
Amortization of intangible assets	178,839	211,234	715,353	844,938
Selling, general and administrative	9,300,359	7,032,067	35,050,817	25,910,757
Total operating expenses	31,176,376	19,863,858	107,134,660	70,773,410
LOSS FROM OPERATIONS	(17,220,289)	(7,826,809)	(64,914,877)	(41,424,327)
OTHER INCOME (EXPENSE):				
Interest and other income	19,483	181,682	288,126	800,785
Interest expense	(3,109,469)	(2,730,890)	(11,985,066)	(8,993,379)
Gain (loss) on extinguishment of debt	991,797	—	991,797	(9,962,495)
Gain on transfer of plasma center assets	—	—	—	11,527,421
Other expense	(89,296)	(185,014)	(128,528)	(227,322)
Other expense, net	(2,187,485)	(2,734,222)	(10,833,671)	(6,854,990)
NET LOSS	$ (19,407,774)	$ (10,561,031)	$ (75,748,548)	$ (48,279,317)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.20)	$ (0.18)	$ (0.88)	$ (0.89)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic and Diluted	96,620,486	59,318,355	86,145,052	54,348,136

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 55,921,152	$ 26,752,135
Accounts receivable, net	13,237,290	3,469,919
Inventories	81,535,599	53,064,734
Prepaid expenses and other current assets	3,046,466	2,533,593
Total current assets	153,740,507	85,820,381
Property and equipment, net	41,593,090	31,741,317
Intangible assets, net	2,444,121	3,159,474
Goodwill	3,529,509	3,529,509
Right-to-use assets	4,259,191	1,245,029
Deposits and other assets	2,106,976	1,595,015
TOTAL ASSETS	$ 207,673,394	$ 127,090,725
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,073,708	$ 9,174,591
Accrued expenses and other current liabilities	8,365,143	4,481,395
Current portion of deferred revenue	142,834	142,834
Current portion of lease obligations	365,682	229,073
Total current liabilities	19,947,367	14,027,893
Senior notes payable, net of discount	92,968,866	68,291,163
Deferred revenue, net of current portion	2,118,698	2,261,532
Subordinated note payable, net of discount	—	14,908,053
Lease obligations, net of current portion	4,334,151	1,302,361
Other non-current liabilities	54,886	106,574
TOTAL LIABILITIES	119,423,968	100,897,576
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS' EQUITY		
Preferred Stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding	—	—
Common Stock - voting, $0.0001 par value, 150,000,000 shares authorized, 104,902,888 and 59,318,355 shares issued and outstanding	10,490	5,932
Additional paid-in capital	428,704,039	290,903,772
Accumulated deficit	(340,465,103)	(264,716,555)
TOTAL STOCKHOLDERS' EQUITY	88,249,426	26,193,149
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 207,673,394	$ 127,090,725